UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,299	07/11/2003	James G. Barsoum	A123 CON	6907

1473 7590 03/09/2005

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS FL C3
NEW YORK, NY 10020-1105

EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,299	BARSOUM ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-29, and 32-33, drawn to a method for increasing the level of a therapeutic gene product in a subject or in a heptocyte population or modulating toxicity associated with a virally encoded transgene, comprising the administration of viral vector encoding the transgene, and an agent that modulates kupffer cell function, and compositions for such methods.

Group II, claim(s) 30-31, drawn to a method for modulating delivery of a virally encoded transgene, comprising identifying a dosage inflection point of the virus, comparing said inflection point to levels of gene product, and adjusting the dose of virus administered.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature shared by the inventions of groups I and II is the administration of a viral vector encoding a transgene and an agent that affects kupffer cell function or levels. Wolff, et al. (1997) J. Virol., 71(1): 624-29 teaches the administration of an adenovirus encoding a transgene and liposomes containing dichloromethylene-bisphosphonate to deliver an absolute increase in transgene expression (ABSTRACT). Moreover, the dichloromethylene-bisphosphonate is taught to lower the levels of kupffer cells (p. 624, paragraph bridging columns). (Applicant should note that Wolff was supplied by Applicant in an IDS, and hence, is not cited on a PTO-892 form, but will be address in the first official action on the merits.) Hence, there is no special technical feature contributed by the present invention over the prior art regarding groups I-II. Hence, as set forth above, each of the groups has a special technical feature not required for the other groups. Thus, groups I-II do not relate to a single general inventive concept under PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR

1.143).Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(1) Applicant is required to choose an agent that affects a Kupffer cell function or lowers the levels of Kupffer cells, from Claims 1 and 3;

(2) Applicant is required to choose one of the fourteen routes of administration for the viral vector encoding the transgene, from Claim 20;

(3) Applicant is required to choose one of the fourteen routes of administration for the agent that affects kupffer cell activity or levels from Claim 21-22; and

(4) Applicant is required to choose a subject that is a:

(i) rodent (Claim 17);

(ii) primate (Claim 18); or

(iii) human (Claim 19).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-33 read on the routes of administration. Claims 1-2, 6-29, and 32-33 read on an agent that affects Kupffer cell function. Claims 3-5 and 37-29 read on an agent that lowers the levels of Kupffer cells. Claims 1-11 and 15-33 read on the administration of the agent less than 24 hours before administration of the vector encoding the transgene. Claims 1-10, 12, and 15-33 read on administration of the agent less than 1 hour before administration of the vector encoding the transgene. Claims 1-17 and 20-33 read on rodents. Claim 1-16, 18, and 20-33 read on primates. Claims 1-6 and 19-33 read on humans.

The following claim(s) are generic: 1, 10, and 20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the special technical feature shared between the agents, is that they affect Kupffer cells. As shown above, by Wolff, such an agent is taught to affect Kupffer cells. The special technical feature shared by the rodents, primates and humans, is that they are all animals. However, Wolff teaches treatment of mice (p. 624, last paragraph). Hence, such is taught by Wolff. Moreover, the differences in administration times can alter the biochemistry, as the chemicals must each of have time to act, and their influence on the other may also be altered by clearance rates. Hence, these differences require different considerations with respect to the biochemistry of the animals and delivery times. Therefore, there is no common general inventive concept shared by each of these species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.
Examiner, USPTO, AU 1632
2C55 Remsen Building
(571) 272-0729

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER